

# PATENT COOPERATION TREATY

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From the  
INTERNATIONAL SEARCHING AUTHORITY

To:

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KAO  
12/5/04 Resp. to Written Opinion  
(Final 11/5/05)

Applicant's or agent's file reference  
see form PCT/ISA/220

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

### FOR FURTHER ACTION See paragraph 2 below

International application No. PCT/US2004/017344	International filing date (day/month/year) 03.06.2004	Priority date (day/month/year) 03.06.2003
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International Patent Classification (IPC) or both national classification and IPC  
G01N21/27

Applicant  
BAYER HEALTHCARE LLC

#### 1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

#### 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

#### 3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**Box No. I Basis of the opinion**

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
  - This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - a sequence listing
    - table(s) related to the sequence listing
  - b. format of material:
    - in written format
    - in computer readable form
  - c. time of filing/furnishing:
    - contained in the international application as filed.
    - filed together with the international application in computer readable form.
    - furnished subsequently to this Authority for the purposes of search.
3.  In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US2004/017344

**Box No. II Priority**

1.  The following document has not been furnished:

copy of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(a)).  
 translation of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2.  This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or  
industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1-30
Inventive step (IS)	Yes: Claims	
	No: Claims	1-30
Industrial applicability (IA)	Yes: Claims	1-30
	No: Claims	

2. Citations and explanations

**see separate sheet**

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Reference is made to the following documents:

**D1:** EP-A-0 646 784 (MILES INC) 5 April 1995 (1995-04-05)  
**D2:** EP-A-0 837 320 (BAYER AG) 22 April 1998 (1998-04-22)  
**D3:** EP-A-0 994 343 (BAYER AG) 19 April 2000 (2000-04-19)  
**D4:** EP-A-1 033 569 (BAYER AG) 6 September 2000 (2000-09-06)  
**D5:** EP-A-1 118 859 (WAKO PURE CHEM IND LTD) 25 July 2001 (2001-07-25)

2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **independent claims 1, 19, 20, 21** is not new in the sense of Article 33(2) PCT.
  - 2.1 The document **D1** discloses (the references in parentheses applying to this document):  
an apparatus (56) suitable for verifying proper operation of an optical inspection machine, comprising: a row of coloured segments (56) that simulate reagent pads containing known types of analytes at known concentrations, wherein the row of coloured segments (56) are positioned so that segments can be illuminated by the read head of the optical inspection machine (see **D1**: figure 3; page 8, lines 3-8).  
The subject-matter of **independent claim 1** is therefore not new (Articles 33(1) and 33(2) PCT).
  - 2.2 The same objections are raised against novelty of **independent claim 1** having regard to the disclosure of documents **D2** to **D5**, see the corresponding passages cited in the search report.
  - 2.3 The same reasoning applies, mutatis mutandis, to the subject-matter of the corresponding **independent claims 19, 20, 21**, which therefore are also considered not new.
3. **Dependent claims 2-17, 20, 22-30** do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, see documents **D1** to **D5** and the corresponding passages cited in the search report.